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GB 2212267 A WO 96/01592 A1 WO 94/00052 A1
WO 93/16641 A1 US 5492131 A

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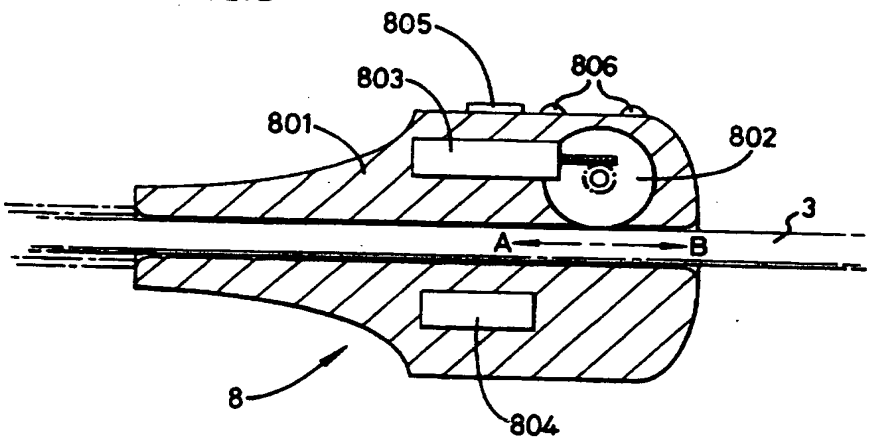
INT CL^6 **A61B 8/12 , A61M 25/01 25/08 25/082**

(54) Abstract Title
Lateral Translation of Ultrasound Imaging Intravascular Catheters

(57) There is provided an intravascular ultrasound visualisation arrangement comprising a catheter 3 with a phased array ultrasonic transducer 4 at or near its distal end 3a, an interface module 5 together with a drive means 8, and a control cart 6. The drive and interface module are located outside the patient and provide a means to move the catheter/transducer solely in a longitudinal direction within a blood vessel or an artery in the patient. In one arrangement the drive is a "pull-back" device 8 and separate from the interface module. The device, which directly engages the catheter, comprises a housing 801, a catheter engaging drive wheel 802, an electric motor 803 operatively connected to said drive wheel and an electric battery 804 all contained within the said housing. A method of imaging a blood vessel or artery whilst the catheter is moving at a uniform speed is also disclosed.

FIG. 3



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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

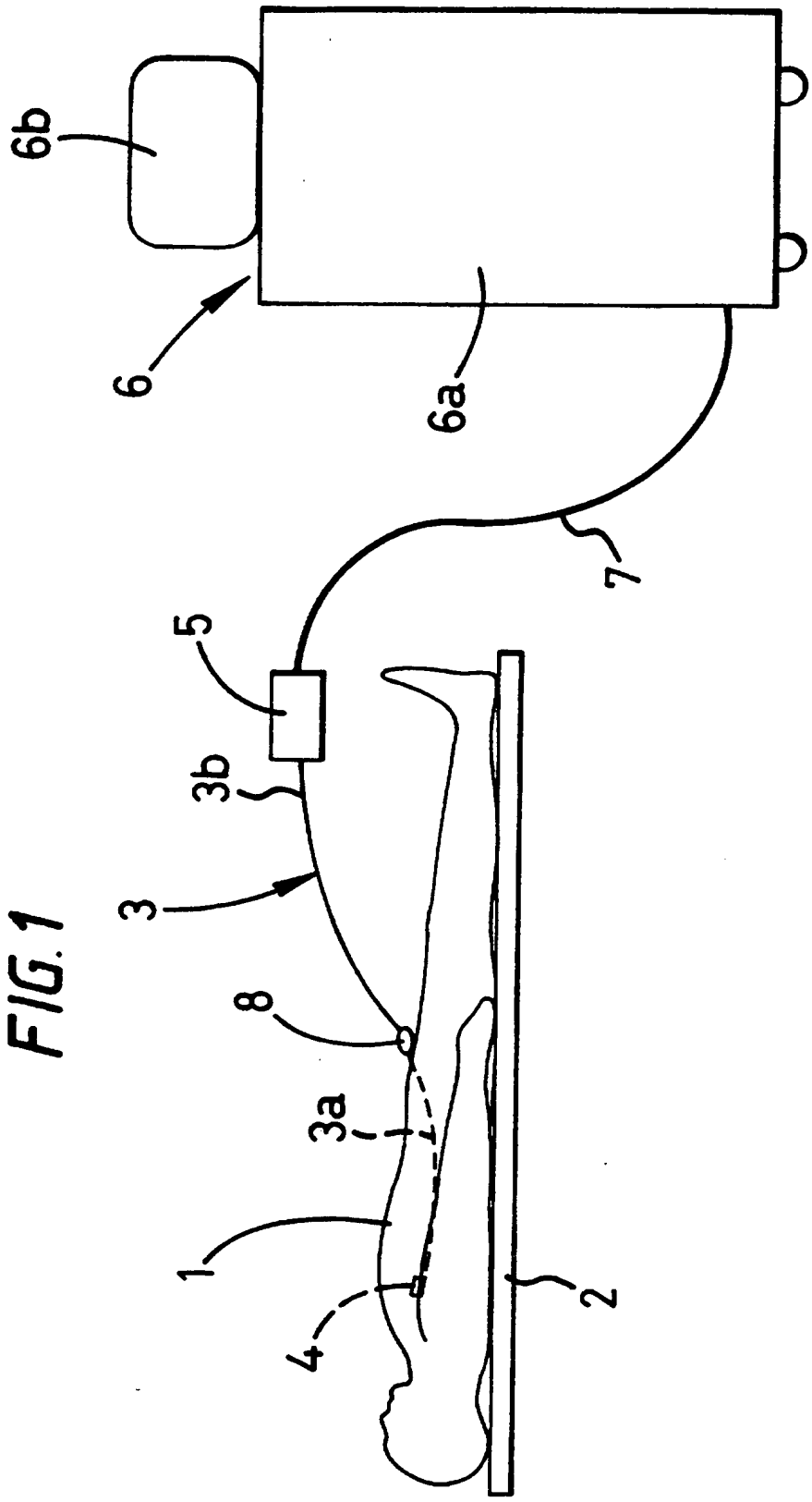


FIG.1

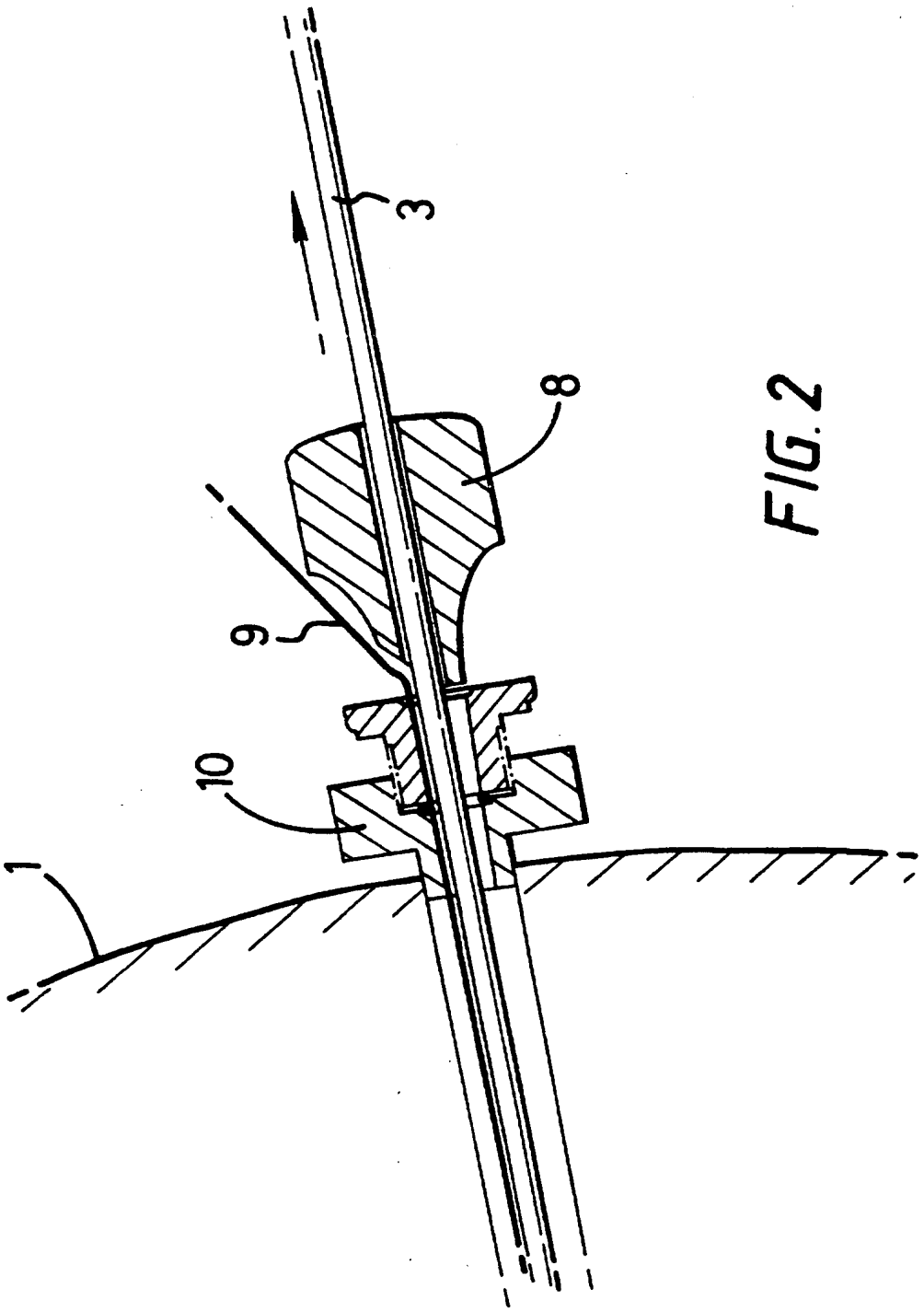


FIG. 2

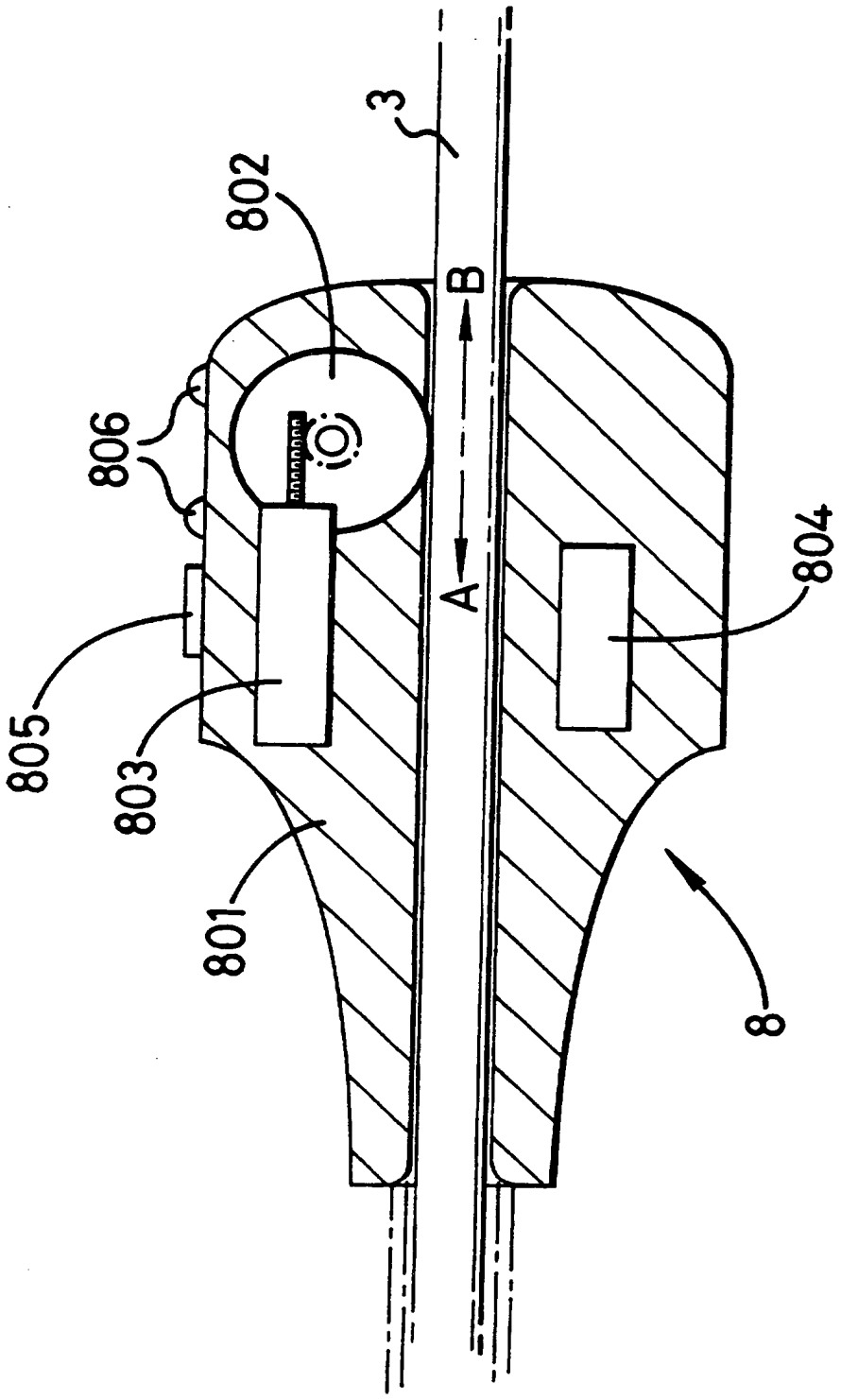
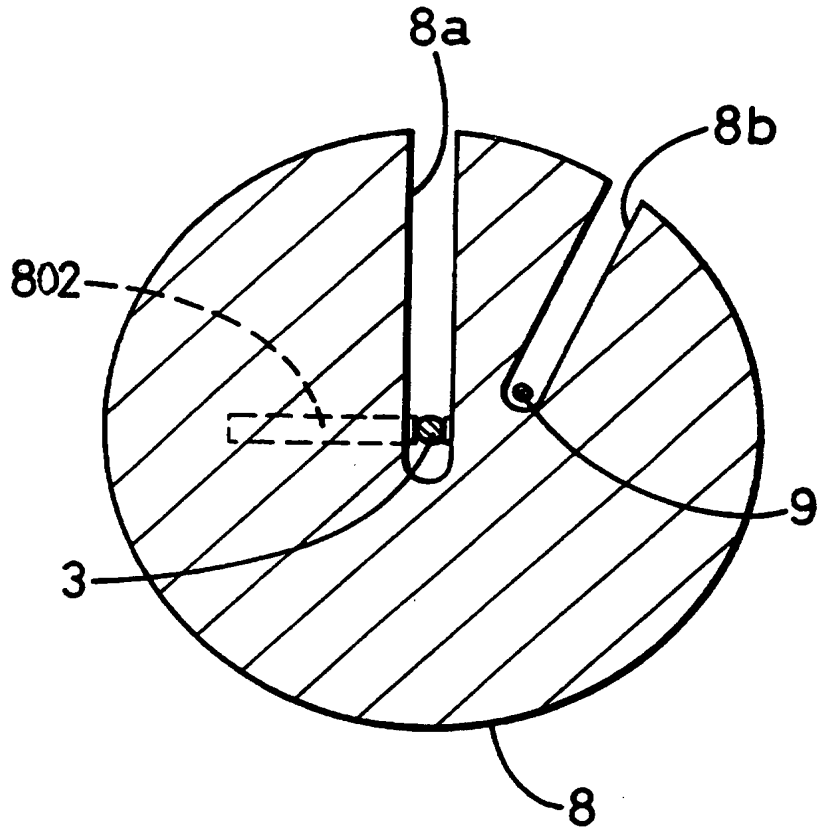


FIG.3

FIG. 4



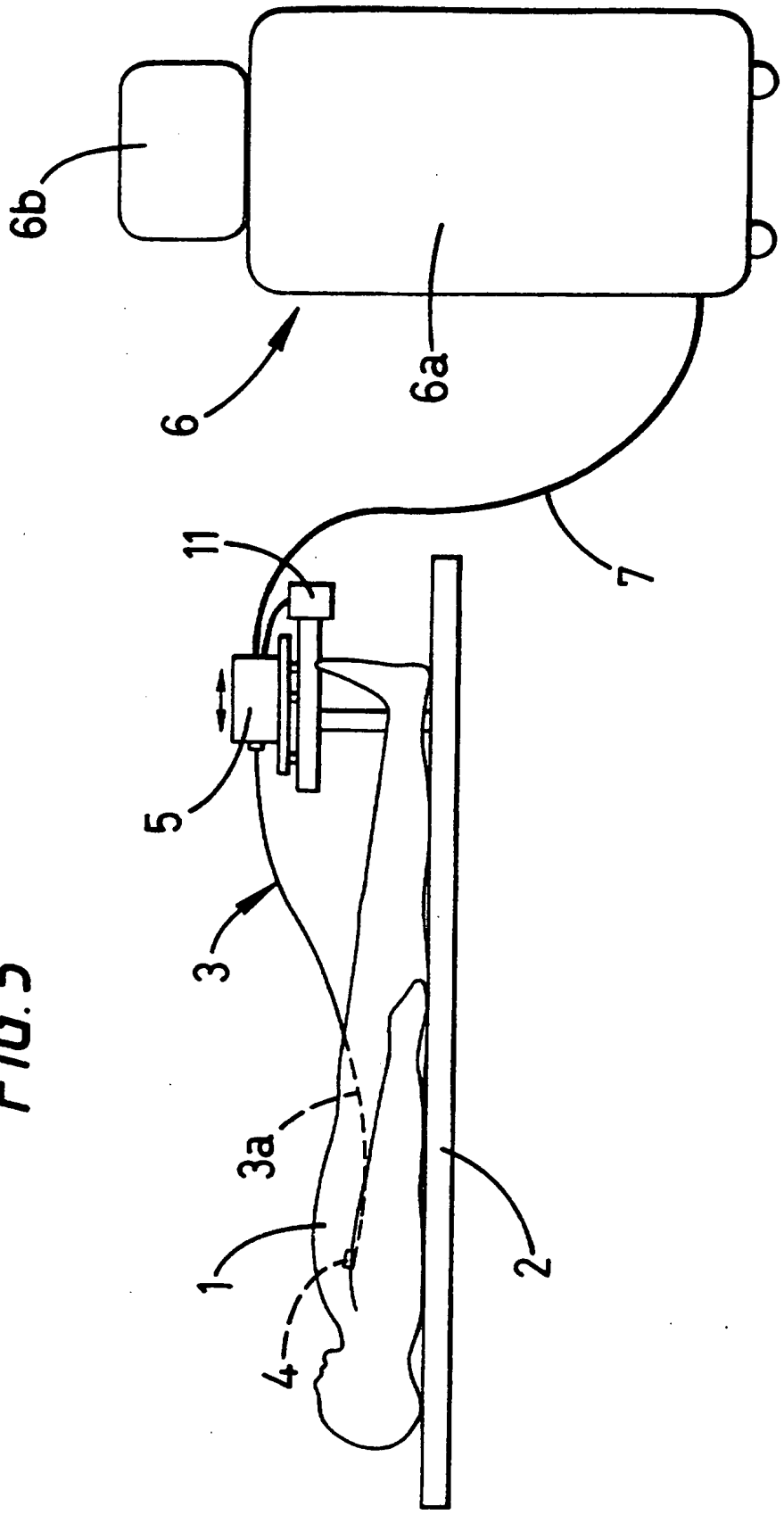


FIG.5

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ULTRA SOUND IMAGING AND CATHETERS THEREFOR

The present invention relates to ultrasound imaging and catheters therefor and more particularly to ultra sound imaging of blood vessels using intravascular catheters.

In our UK Patent No. 2,233,094 we disclose a system capable of producing real time two-dimensional images of the vessel cross-section.

In our UK Patent No. 2,221,267 we disclose a method of obtaining three-dimensional views of an artery by obtaining a series of two-dimensional slices at intervals which slices have been created by translating the catheter along the artery. This gives the advantage of providing information on the longitudinal extent of lesions.

A known way of producing the translation is to use a motorised pull-back device, often under system control, an example of which is disclosed in U.S. Patent No. 5,592,942.

For devices used with rotary transducer catheters the transducer drive unit is also moved.

The motor drive of such a unit is generally large and thus difficult to make disposable or so that it is re-sterilisable and, therefore, in practice such devices

are generally used unsterile and separated from the sterile area around the patient by placing in a sterile wrap. Power has to be provided to the motor drive, and the whole arrangement is inconvenient.

A further cause of inconvenience is that the drive has to connect with the sheath insertion valve, (referred to as a Tuey valve) to ensure that the catheter itself is moved and not the drive unit.

The present invention is concerned with overcoming or at least reducing these problems.

According to the present invention in an ultrasonic visualising system employing a non-rotatable ultrasonic transducer arrangement mounted on or near the distal end of a catheter adapted to be inserted into the artery of a patient, there is provided drive means located up-stream of the entry point of the catheter into the patient which drive means is adapted to drivably engage the catheter in order to move it length-wise to adjust the position of the transducer arrangement within the patient.

According to the present invention a device for use in moving a catheter longitudinally within a patient comprises a housing adapted to fit over or have a catheter pass therethrough, a catheter engaging drive member mounted in the housing, an electric motor mounted in the housing and operatively connected to the said drive member, an electric battery or batteries or a mounting for

such within the housing, and a control device to enable the drive member to be driven to move the catheter either into or out of the patient.

How the invention may be carried out will now be described by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a general diagrammatic view of one arrangement according to the present invention;

Figure 2 is a greatly enlarged view showing the area of figure 1 containing the pull-back device and the catheter point of entry into the patient;

Figure 3 shows the pull-back device itself in more detail;

Figure 4 is a cross-sectional diagrammatic view of an alternative construction of pull-back device; and

Figure 5 is a view similar to figure 1 but showing another pull-back arrangement according to the present invention.

Figure 1

A patient 1 is supported on an operating table 2 and has inserted into an artery (typically in the groin) a catheter 3, that part of the catheter being located within the patient's body being shown in broken lines.

Typically the distal end 3a of the catheter will be fed into the patient through an incision in the groin so that the distal end will become located within an arterial passage in or near the patient's heart.

The distal end 3a of the catheter carries a phased array ultrasonic transducer arrangement 4 images of the interior of the patient's arterial passages may be obtained to assist the clinician in diagnosis and treatment.

The proximal end 3b of the catheter plugs into an interface module 5 in known manner, the module being connected to a control/display cart 6 by means of an "umbilical" composite cable 7. The cart 6 consists of a cabinet 6a which contains all the ultrasonic signal transmission/receiving/processing hardware and software and has a cathode ray tube monitor 6b mounted on it.

A pull-back device 8, according to the present invention, is positioned close to the point at which the catheter 3 enters the patient 1.

Figure 2

This shows in more detail and on the greatly enlarged scale the situation at the point where the catheter 3 enters the patient 1.

At this point the catheter 3, and its associated guide wire 9, pass through a non-return valve 10, known as a "Tuey valve", in known manner.

The purpose of the valve is to allow the catheter to enter the sheath, and prevent blood escaping.

The pull-back device 8 is positioned adjacent and up-stream of the Tuey valve 10, both being located in a sterile area adjacent to the patient. Any article in this area must be sterile or be housed in a sterile wrap.

The purpose of the pull-back device 8 is to drive the catheter 3 in the direction of the arrow in figure 2 so that the ultrasonic transducer phased array at or near its distal end will be moved progressively along that part of the patient's artery which the clinician needs to have visualised.

In this embodiment the pull-back device 8 is self-contained with its own power supply and is shown in more detail in figure 3 which will now be referred to.

Figure 3

The pull-back device 8 comprises housing 801 which contains a catheter-engaging driving wheel 802, an electric motor 803, a battery pack 804 and an LCD display 805 together with control buttons 806 by which the drive wheel 802 can be rotated in a clockwise or anti-clockwise direction to move the catheter in the direction of either arrow A or arrow B in figure 3.

This embodiment of pull-back device has the following features:

a. the device is operated by the clinician who inserts the catheter 3;

b. the device is sterile and single-use and no sterile wrap is needed;

c. the guide wire 9 is held by the clinician who also retains feel of the catheter 3;

d. the device requires no external power leads or control leads to connect it to the system;

e. there is no slack to take up between the patient and the pull-back device;

f. The device withdraws the catheter at a pre-determined constant rate.

One of the disadvantages of this embodiment is that if the catheter is inserted without threading it through the pull-back device, and a pull-back acquisition is required, then the catheter must be withdrawn to install the pull-back device, i.e. the pull-back device needs to be slid over the catheter before the distal end of the latter is inserted into the patient.

One possible way of overcoming this problem would be to make the pull-back device sufficiently cheap for it to be pre-installed on each catheter. With such an arrangement the pull-back device would be installed at the proximal end of the catheter and could then be moved into a position by using its motor to drive it along the catheter to the desired position adjacent the patient as shown in figure 1.

One feature of having a disposable pull-back device is that it relies on the uniform withdrawal speed and the imaging system calculating the distance travelled based on elapsed time. This will not allow ECG gating of the motion which some users have recommended to reduce pressure related variation of the vessel diameter, and the saw-tooth appearance this can give in a longitudinal view.

During the cardiac cycle the normal physiological variation in coronary artery diameter can be as much as 15% between diastole and systole, as the vessel expands and contracts accordingly. Given that the likely pull-back velocity is significantly less than that of the vessel wall, any series of consecutively

captured cross-sectional images will display this variation. In particular, when re-formatting the subsequent 3-D data set to show longitudinal views of the vessel (that is planes orthogonal to the capture slices) this variation manifests as a jagged, saw-tooth representation of those smooth interfaces and surfaces of the vessel that run parallel to the catheter movement.

In this prior art a stepwise motion is used with the motor producing a fixed motion on each ECG trigger. This has the potential disadvantage of the stop-start motion causing backlash errors. A better method is to record the ECG simultaneously with the images during pull-back, using a digital image recording method as described in our UK Patent application no
then retrospectively select images at both regular intervals and similar ECG phases. In this way the images can be ECG gates without the need for ECG triggered motion.

Alternatively the device could have the construction which will now be described with reference to figure 4.

Figure 4

The housing of the pull-back device is provided with two channels 8a and 8b into which the catheter 3 and guide wire 9 respectively may be introduced and positioned in the locations indicated in figure 4 without having to thread the catheter through the pull-back device. This not only allows the catheter to be

slotted into the pull-back device when ready for use but also allows the guide wire to be neatly stowed into position.

A further solution (not illustrated) is to construct the body of the pull-back device in two portions which could be hinged to one another (rather like a clam shell) so that the pull-back device can be installed after the catheter has itself been installed.

Figure 5

This figure illustrates another embodiment of the present invention and in particular illustrates a different solution to the problem of maintaining a sterile field in the vicinity of the patient.

Items equivalent to those shown in figure 1 have been given the same reference numerals.

In this second embodiment the pull-back device is in effect incorporated in the interface module 5 in that that module is mounted on a carriage 11 which is provided with motive power, e.g. an electric motor, by which the carriage 11 and thus the interface module 5 and thus, in turn, the catheter 3 can be pulled to progressively move the distal end and associated ultrasonic phased array within the patient's artery.

With this arrangement the interface module/unit is raised off the patient's bed whereas in the prior art arrangements the interface module would normally just rest on the patient's bed or operating table.

By being raised off the sterile surface the interface module 5 would not require covering with a sterile wrap which could impede the insertion of the catheter 3 into the patient. Furthermore the length of the phased away catheter can typically be greater than the equivalent rotary transducer catheter, allowing the interface module to be further from the patient.

Some of the advantages of this second embodiment are:

i. the pull-back device can be operated from the cart 6, by the cart operator rather than by the clinician;

ii. the pull-back device obtains its power from the interface module;

iii. the position of the catheter can be displayed on the cart monitor.

CLAIMS

1. In an ultrasonic visualising system employing a non-rotatable ultrasonic transducer arrangement mounted on or near distal end of a catheter adapted to be inserted into the artery of a patient, there is provided drive means located up-stream of the entry point of the catheter into the patient which drive means is adapted to drivably engage the catheter in order to move it length-wise to adjust the position of the catheter arrangement within the patient.

2. A device for use in moving a catheter longitudinally within a patient comprises a housing adapted to fit over or have a catheter pass therethrough, a catheter engaging drive member mounted in the housing, an electric motor mounted in the housing and operatively connected to the drive member, an electric battery or batteries or a mounting for such within the housing, and a control device to enable the drive member to be driven to move the catheter either into or out of the patient.

3. The device as claimed in Claim 2 including a manual switch control to control the energisation of the motor.

4. An device as claimed in claim 2 having means to drive the catheter at constant speeds, there being no connection to an imaging system.

5. A device as claimed in Claim 2 including an automatic system for controlling the energisation of the motor.

6. A device as claimed in any one of Claims 2 to 5 having a display on the housing to indicate the position of the catheter.

7. A device as claimed in Claim 6 in which the display is a liquid crystal display.

8. A device as claimed in any one of Claims 2 to 7 in which the housing is provided with a slot to enable the device to be engagingly mounted on the catheter without the necessity of the catheter having to be threaded through the device.

9. A device as claimed in any one of Claims 2 to 7 in which the housing comprises at least two interconnected parts so that the housing can be closed around the catheter to bring it into driving engagement therewith without the need to thread the catheter through the device.

10. A device as claimed in any one of Claims 2 to 9 in combination with and mounted on a catheter.

11. An arrangement as claimed in Claim 1 including an interface module into which the proximal end of the catheter is adapted to be mounted, the module having means whereby it may be moved relatively to the patient in order to move the distal end of the catheter along the patient's vessel or artery.

12. An arrangement as claimed in Claim 11 including a carriage adapted to carry the module.

13. An arrangement as claimed in Claim 11 or 12 including a control cart which is adapted to supply power to the module and device and whereby a cart operator can control the pull-back device in order to move the catheter with respect to the patient.

14. An arrangement substantially as hereinbefore described with reference to and as shown in figures 1 to 3 of the accompanying drawings.

15. An arrangement as claimed in Claim 13 as modified by figure 4 of the accompanying drawings.

16. An arrangement substantially as hereinbefore described with reference to and as shown in figure 5 of the accompanying drawings.

17. A pull-back device substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

18. A method of reconstructing a longitudinal section of the vessel in which the transverse images are stored at regular intervals in time, whilst the catheter is being pulled back at a uniform speed.

19. A method as claimed in claim 18 in which the said images are combined with an ECG waveform.

20. A method as claimed in claim 19 in which corresponding to both the same ECG phase and regular intervals in position are selected from the stored set of images to produce a 3-D reconstruction of the vessel.

The Patent Office

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Application No: GB 9718984.9 **Examiner:** Simon M. Fortt
Claims searched: 1, 11-13, 14-16 in part. **Date of search:** 26 January 1998

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5R (RGBB, REP, REKX)

Int Cl (Ed.6): A61B 8/12; A61M 25/01, 25/08, 25/082.

Other: Online: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X Y	GB 2 212 267 A	(CIRCULATION RESEARCH LTD) whole document	1, 11-13
Y	WO 96/01592 A1	(KARL STORZ GMBH & CO.) abstract; p 7, ll 18-22; figs.	1
X Y	WO 94/00052 A1	(CARDIOVASCULAR IMAGING SYSTEMS INC.) p 5, ll 2-19; p 5, ll 31-33; p 19, l 12 - p 22, l 3; figs., particularly 8A-8C.	1, 11-13
A	WO 93/16641 A1	(DIASONICS INC.) p 6, ll 2-8; p 28, l 4 - p 30, ll 10; figs.1, 3, 4, 14 and 18.	
Y	US 5 492 131	(GALEL) col. 2, ll 12-34; col. 3, ll 5-10, ll 28-31; col. 4, ll 9-13; fig., claim 1.	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.